

WHAT WE CLAIM IS:

1. A method of treating a cyclooxygenase-2 dependent disorder or condition comprising:
5 administering 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof in an amount effective to treat said disorder or condition for about 24 hours, comprising administering orally once a day to a human in need of such treatment one or more immediate release pharmaceutical compositions comprising 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof.
- 10 2. The method of claim 1, wherein said immediate release pharmaceutical composition does not comprise sufficient water-insoluble or polymeric components to impart extended release characteristics to said composition.
- 15 3. The method of claim 1, wherein said effective amount is between about 200 and about 1200 mg.
4. The method of claim 1, wherein said effective amount is between about 200 and about 600 mg.
- 20 5. The method of claim 1, wherein said effective amount is between about 200 and about 400 mg.
6. The method of claim 1, wherein said effective amount is about 200 mg.
- 25 7. The method of claim 1, wherein said effective amount is about 400 mg.
8. The method of claim 3, wherein said immediate release pharmaceutical composition comprises between about 50 and about 800 mg of said 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof.
- 30 9. The method of claim 4, wherein said immediate release pharmaceutical composition comprises between about 50 and about 600 mg of said 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof.

10. The method of claim 5, wherein said immediate release pharmaceutical composition comprises between about 50 and about 400 mg of said 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof.

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11. The method of claim 6, wherein said immediate release pharmaceutical composition comprises about 200 mg of said 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof.

10 12. The method of claim 7, wherein wherein said immediate release pharmaceutical composition comprises about 400 mg of said 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof.

15 13. The method of claim 6, wherein said pharmaceutical composition is a tablet.

14. The method of claim 7, wherein said pharmaceutical composition is a tablet.

15 15. The method of claim 8, wherein said pharmaceutical composition is a tablet.

20 16. The method of claim 9, wherein said pharmaceutical composition is a tablet.

17. The method of claim 10, wherein said pharmaceutical composition is a tablet.

18. The method of claim 11, wherein said pharmaceutical composition is a tablet.

25 19. The method of claim 12, wherein said pharmaceutical composition is a tablet.

20. A composition for treating a cyclooxygenase-2 dependent disorder or condition comprising:

30 one or more immediate release pharmaceutical compositions comprising 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof, said one or more immediate release pharmaceutical compositions comprising an effective amount of 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a

pharmaceutically acceptable salt thereof to treat said disorder or condition for about 24 hours; and

printed instructions directing that said one or more immediate release pharmaceutical compositions comprising 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof be administered orally once a day.

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21. The composition of claim 20, wherein said immediate release pharmaceutical composition does not comprise sufficient water-insoluble or polymeric components to impart extended release characteristics to said composition.

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22. The composition of claim 20, wherein said immediate release pharmaceutical composition comprises between about 50 and about 400 mg of said 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof.

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23. The composition of claim 20, wherein said immediate release pharmaceutical composition comprises between about 50 and about 600 mg of said 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof.

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24. The composition of claim 20, wherein said immediate release pharmaceutical composition comprises between about 50 and about 1200 mg of said 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof.

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25. The composition of claim 20, wherein said immediate release pharmaceutical composition comprises about 400 mg of said 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof.

26. The composition of claim 20, wherein said immediate release pharmaceutical composition is a tablet.

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27. The composition of claim 21, wherein said immediate release pharmaceutical composition is a tablet.

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28. The composition of claim 22, wherein said immediate release pharmaceutical composition is a tablet.

29. The composition of claim 23, wherein said immediate release pharmaceutical composition is a tablet.

5 30. The composition of claim 24, wherein said immediate release pharmaceutical composition is a tablet.

10 31. The composition of claim 20, wherein said immediate release pharmaceutical composition does not comprise sufficient water-insoluble or polymeric components to impart extended release characteristics to said composition.

15 32. A method of achieving inhibition of cyclooxygenase-2 in a human subject over a period of about 24 hours comprising administering a single daily dose of 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof, which dose is effective for inhibiting cyclooxygenase-2 over a period of about 24 hours without the use of a sustained release formulation.

20 33. A method of achieving a prophylactic or therapeutic effect in a cyclooxygenase-2-mediated disorder or condition in a human subject over a period of about 24 hours, which method comprises administering to a subject in need of such treatment a single daily dose of 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid or a pharmaceutically acceptable salt thereof, which dose is effective over a period of about 24 hours without the use of an extended release formulation.

25 34. The composition of claim 20, wherein said immediate release pharmaceutical formulation comprises microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, povidone, titanium dioxide, and magnesium stearate.

30 35. The composition of claim 34, wherein said immediate release pharmaceutical formulation comprises about 200 mg of 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid, about 103.4 mg of microcrystalline cellulose, about 46.6 mg of lactose, about 16 mg of povidone, about 16 mg of titanium dioxide, about 16 mg of croscarmellose sodium, and about 2 mg of magnesium stearate.

36. A pharmaceutical composition comprising an effective amount of 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid and between 0.01 and 2% by weight of 5-methyl-2-(2'-chloro-6'-fluoroanilino)benzyl alcohol.

5 37. A pharmaceutical composition according to claim 36 wherein said pharmaceutical composition is a tablet.

10 38. A pharmaceutical composition according to claim 37 additionally comprising microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, povidone, titanium dioxide, and magnesium stearate.